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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,606	05/05/2005	Maria Cristina Geroni	17703 (PC27210A)	4724
7590	06/23/2010		EXAMINER	
Peter I Bernstein Scully Scott, Murphy & Presser 400 Garden City Plaza Suite 300 Garden City, NY 11530			WEBB, WALTER E	
			ART UNIT	PAPER NUMBER
			1612	
			MAIL DATE	DELIVERY MODE
			06/23/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/500,606	GERONI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 March 2010.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,5-9,13-15,24-27,31 and 32 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,5-9,13-15,24-27,31 and 32 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Applicants' arguments, filed 3/22/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112—New by amendment***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-7, 9, 13-15, 24-27, 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 5-7, 9, 13-15, 24-27, 31 and 32 each recites the limitation "acryloyl distamycin derivative". There is insufficient antecedent basis for this limitation in the claims.

### ***Claim Rejections - 35 USC § 103 --previous***

Claims 1, 5-9, 13-15, 24-27, 31 and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cozzi et al. (WO 98/04524, published February 5, 1998) in view of Cortes et al. (Investigational New Drugs 2000).

Applicant argues that the claims as amended are commensurate in scope with the Exhibit I data showing a synergistic result. The Exhibit I data shows three tables. In each table one compound of formula I (Brostallicin) is combined with either STI571, ZD1839 or OSI-774. The combination of Brostallicin and STI571 was tested against K562 human CML (leukemia) cell line. The combination of Brostallicin and ZD1839 was tested against H322M human lung cancer cell line. The combination of Brostallicin and OSI-774 was tested against MDA-MB-468 human breast carcinoma cell line. The data shows a more than additive effect for each combination. It is also noted that for each table the ratio, and cancer type varied for each combination. However, the instant claims are not commensurate in scope with these data.

The instant claims read very broadly, encompassing compounds of the general formula I in combination with either STI571 or OSI-774 that were not tested. The instant method claims are also not limited to a specific type of cancer. Instead the method claims recite treating tumors of the colon, ovary, kidney, liver, stomach, and brain, and melanoma. It is not clear whether the *in vitro* data showing synergy at specific ratios for the combination of Brostallicin with either STI571 or ZD1839 can be seen with these other types of cancer. The data of Exhibit I do not provide an adequate basis for concluding that the great number of combinations recited in the generic claims would behave in the same way, especially in regard to neoplastic disease states in general. In regard to the *in vivo* method claims, there is also no recitation of concentration ranges or ratios of the combinations that are necessary to produce the same results of the *in vitro* data. It appears that the ratios for the combination of Brostallicin and either STI571

or ZD1839 are important for the synergistic effect, since the ratios varied for each of the cell lines tested. Accordingly, the instant claims remain rejected as being obvious over Cozzi in view of Cortes.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb  
/Walter E Webb/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612